

STATE OF CALIFORNIA  
FISH AND GAME COMMISSION  
INITIAL STATEMENT OF REASONS FOR REGULATORY ACTION  
(Pre-publication of Notice Statement)

Add new Section 1.92, and add new subsection (11) of Section 671(c)  
Title 14, California Code of Regulations

Re: Define the term Transgenic, and add transgenic aquatic animals to the list of live animals restricted for importation, transportation and possession

I. Date of Initial Statement of Reasons: November 4, 2002

II. Dates and Locations of Scheduled Hearings:

(a) Notice Hearing: Date: October 25, 2002  
Location: Crescent City

(b) Discussion Hearing: Date: December 5, 2002  
Location: Monterey

(c) Adoption Hearing: Date: February 6, 2003  
Location: Los Angeles/San Pedro

III. Description of Regulatory Action:

(a) Statement of Specific Purpose of Regulation Change and Factual Basis for Determining that Regulation Change is Reasonably Necessary:

Transgenic species are an example of bioengineered products that are produced under artificial conditions with the goal of enhancing yield or some other economically important biological trait. For example, many US agricultural plant crops include bioengineered varieties that are resistant to insects or viruses. Transgenic manipulation involves transferring genetic material (DNA) from one species into chromosomes of another. The resulting genetic makeup is unique and the transgenic organisms have no genetic counterparts in natural systems. Because of their novel genetic structure, transgenic species should be considered "non-indigenous", and potentially detrimental to native species.

There are no transgenic animals currently approved for agriculture production in the US. Research, development, and commercial use of transgenic organisms are currently governed at the Federal level. For use of transgenic animals beyond confined laboratory research, (that is for production, sale, and distribution) approval must first be obtained from the

Federal Food and Drug Administration (FDA). FDA has taken the position that transgenic animals contain a new animal drug that must be FDA approved before they may be used commercially. The requirement for FDA approval of new animal drugs applies to both food and non-food animals. The National Environmental Protection Act (NEPA), provides for environmental assessment as part of the drug approval process and provides the mechanism for coordination with other federal agencies. FDA is currently evaluating an application for transgenic Atlantic salmon for human consumption and is consulting with NMFS, USFWS and EPA in review of potential environmental impacts that might result if that application is approved.

Even though there is no current opportunity, outside of the research community to produce transgenic fish, it is clear that there is both interest in developing these fish, and concern about potential environmental impacts. The California legislature considered legislation in 2002 that would have placed a moratorium on importation of transgenic animals into the State. This legislation did not succeed. Also expressing concern over the growing interest in production and distribution of transgenic organisms, the American Fisheries Society, an organization of fishery professional, issued a policy statement regarding transgenic fishes that “advocates caution in uses of transgenic fishes . . .”, and that “introduction of such fishes into natural aquatic communities may cause ecological or genetic impacts.”

In view of the increasing interest and concern relative to transgenic animals, the Department recommends that the Commission consider regulations appropriate to monitor the use of transgenic fish in research and to impose restrictions on commercial uses appropriate to ensure against detrimental impacts to California’s fish and wildlife resources..

To make clear, and explicit, the authority to allow or deny use of transgenic fish species, the Department recommends that transgenic fish be added, as a general category, to the Commission’s list of restricted species in Section 671, Title 14, CCR. The Department has already drafted changes to the application form used for live fish importation permits. The change will require applicants to disclose the transgenic nature of the fish applied for.

The definition of transgenic that is to be used in the context of these regulations is being developed by interested persons from the Department, academia, legislature representatives, the aquaculture industry, and other interested parties. This definition is expected to be completed by December 5, 2002.

- (b) Authority and Reference Sections from Fish and Game Code for Regulation:

Authority: Sections 2118 and 2120, Fish and Game Code.

Reference: Sections 1002, 2116, 2118, 2118.2, 2118.4, 2119-2155, 2190, 2271, 3005.9 and 3005.92, Fish and Game Code.

- (c) Specific Technology or Equipment Required by Regulatory Change: None.
- (d) Identification of Reports or Documents Supporting Regulation Change: None.

- (e) Public Discussions of Proposed Regulations Prior to Notice Publication:

Dates and Locations of Scheduled Hearings:

Date: December 5, 2002

Location: Monterey

Date: February 6, 2002

Location: Los Angeles/San Pedro

IV. Description of Reasonable Alternatives to Regulatory Action:

- (a) Alternatives to Regulation Change:

Establish a moratorium on the importation or possession of all transgenic aquatic animals within the State for an indefinite period.

- (b) Consideration of Alternatives: A moratorium on the importation or possession of transgenic aquatic animals would ensure the protection of natural aquatic animal populations within the State. However, a moratorium would prevent research and the subsequent discovery of potential benefits that transgenic species may provide.

V. Mitigation Measures Required by Regulatory Action:

The proposed regulatory action will have no negative impact on the environment; therefore, no mitigation measures are needed.

VI. Impact of Regulatory Action:

The potential for significant statewide adverse economic impacts that might result from the proposed regulatory action has been assessed, and the following initial determinations relative to the required statutory categories have been made:

- (a) Significant Statewide Adverse Economic Impact Directly Affecting Businesses, Including the Ability of California Businessmen to Compete with Businesses in Other States: The proposed action will not have a significant statewide adverse economic impact affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed change will provide for continued research and development of transgenic aquatic organisms under safeguards appropriate to protect the wildlife resources of the State.
- (b) Impact on the Creation or Elimination of Jobs Within the State, the Creation of New Businesses or the Elimination of Existing Businesses, or the Expansion of Businesses in California: None.
- (c) Cost Impacts on Private Persons: The agency is not aware of any cost impacts that a representative private person would necessarily incur in reasonable compliance with the proposed action.
- (d) Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.
- (e) Other Nondiscretionary Costs/Savings to Local Agencies: None.
- (f) Programs Mandated on Local Agencies or School Districts: None.
- (g) Costs Imposed on Any Local Agency or School District that is Required to be Reimbursed Under Part 7 (commencing with Section 17500) of Division 4: None.
- (h) Effect on Housing Costs: None.

### **Informative Digest/Policy Statement Overview**

Transgenic species are an example of biotechnological products that are produced under artificial conditions with the goal of enhancing yield or some other economically important biological trait. For example, some aquaculturists are interested in creating a transgenic fish product that grows faster than a natural fish. Transgenic manipulation involves incorporating genetic material (DNA) from one species into chromosomes of another. The resulting genetic makeup is unique and these biotechnologically constructed organisms have no genetic counterparts in natural systems. Because of their novel genetic structure, transgenic species should be considered “non-indigenous”, and potentially detrimental to native species.

To make clear, and explicit, the authority to allow or deny use of transgenic fish species, the Department recommends that transgenic fish be added, as a general category, to the Commission’s list of restricted species in Section 671, Title 14, CCR. The Department has already drafted changes to the form used for live fish importation. The change will require applicants to disclose the transgenic nature of the fish applied for.

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